



AF/3728

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
APPEAL TO BOARD OF PATENT APPEALS AND INTERFERENCES**

In re Application of:

John D.Kavelage et al.

Examiner: David Fidei

Serial No.: 09/734,196

Group Art Unit: 3728

Filed: December 12, 2000

Title: SEALED BLISTER ASSEMBLY

APPELLANT'S BRIEF

Assistant Commissioner for Patents
Washington, D.C. 20231

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Sirs:

1. REAL PARTY IN INTEREST

The real party in interest is Multi-Comp, Inc., the assignee of record in connection with this application.

2. RELATED APPEALS AND INTERFERENCES

There are no related appeals and interferences

3. STATUS OF CLAIMS

Claims 1-17 are pending in this application. Claims 1-17 are presently standing under a rejection by the Examiner. The rejection of claims 1-17 is appealed herein.

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4. STATUS OF AMENDMENTS

All amendments requested by Applicant are under consideration and have been entered. The amendments filed subsequent to final rejection in the originally-filed application have been entered and considered in connection with the request for continued examination.

5. SUMMARY OF INVENTION

The present invention relates to a sealed blister assembly wherein the plastic sheet and plastic lid join together to form an impermeable seal. Claims 1-12 and 16 are directed to sealed blister assemblies generally. Claims 13-15 and 17 are directed to package assemblies for dispensing a pharmaceutical medication. As is evident from the drawings and discussion in the application, the assembly for dispensing a pharmaceutical medication is a preferred embodiment of the present invention.

Applicant has devised a new construction that has potentially substantial commercial application, because it is a simple way to obtain an impermeable seal. Applicant is waiting for positive words from the Patent Office before commercializing the invention out of fear of being overwhelmed by large manufacturers if there is no protection of the invention.

Specifically, the invention relates to an assembly that has two fundamental components -- a blister sheet with recesses and a lid sheet with raised ridges. The recesses have a perimeter around the openings into the recesses. The perimeter comprises an undercut made up of sidewalls. Ridge walls of the lid engage the side walls of the undercut on the sheet to form an impermeably sealed blister.

The claimed invention is most easily understood with reference specifically to Figures 2 and 3 as reproduced and blown up below. The figures are labeled in accordance with the detailed explanation in the specification at the bottom of page 4 through page 5 of the application. The plastic sheet 11

includes a recess 13. The recess includes an undercut 21 defined by sidewalls 23. The plastic lid 12 has a raised ridge 22 defined by ridge walls 24.

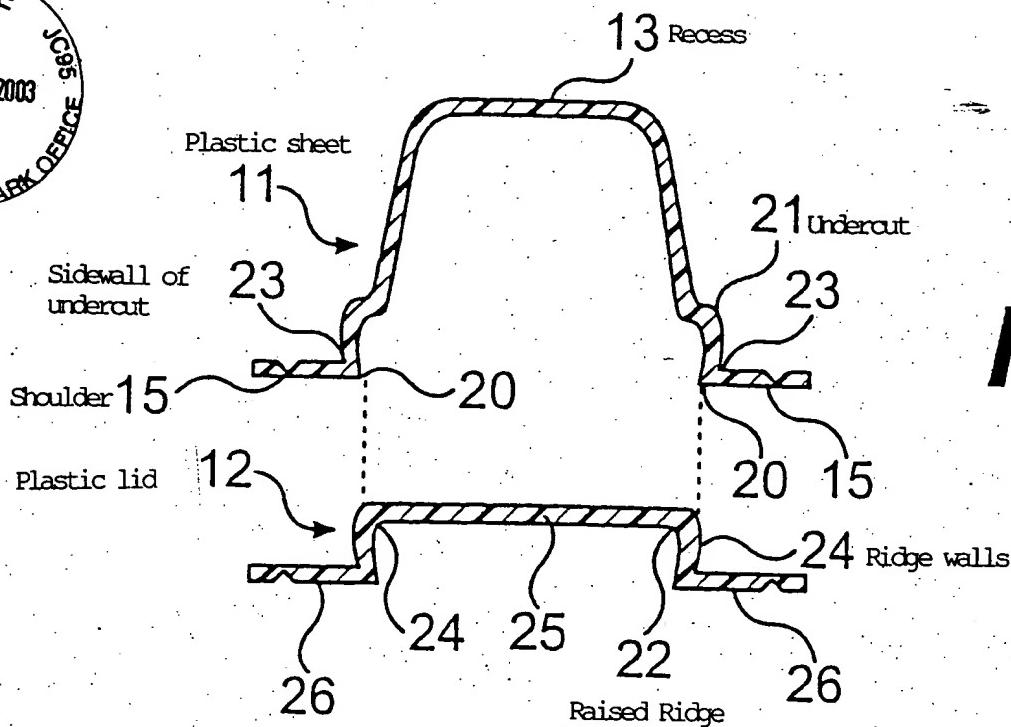
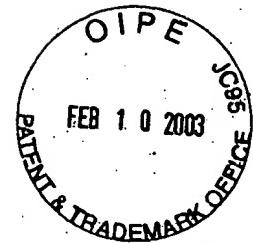


FIG. 2

The frictional engagement of side walls 23 and ridge walls 24 creates an impermeable seal. This frictional engagement is circled and highlighted in Figure 3 as follows:

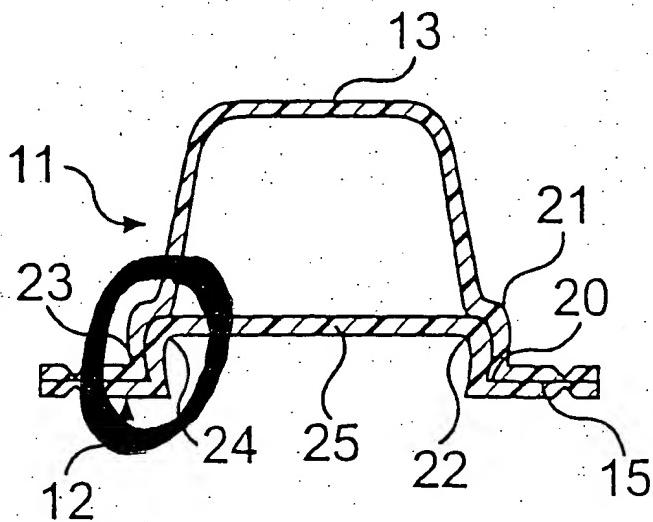


FIG. 3

It is important to emphasize, as Applicant did in an earlier amendment, that the seal created by engagement of the walls is impermeable. The preferred embodiment, as in the example and test in the application, is as a medication package. There are strict and special requirements with respect to this packaging. The packaging cannot be used and sold if it performs at less than rigorous impermeability requirements.

Additional features of the invention shown in Figures 2 and 3 include the flare characteristics of side walls 23 and ridge walls 24. A unique extension of a benefit of this flare characteristic is shown in Figure 5 and in the discussion in the specification on page 6. The undercut side walls 23 are shorter than the ridge walls 35 so that the gap 36 is created.

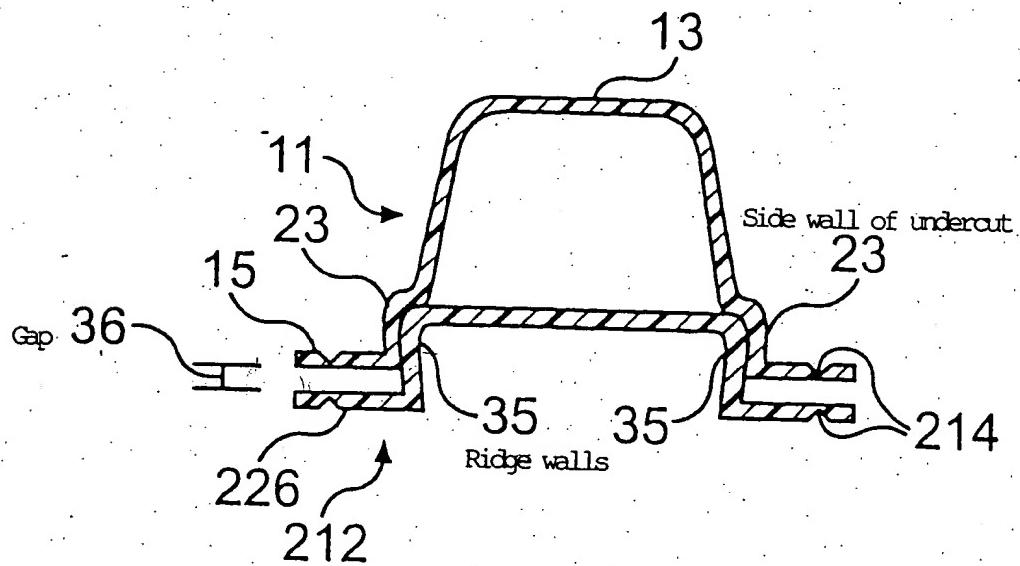


FIG. 5

A benefit of the creation of this gap 36 is to facilitate the separation of individual blisters from a blister package similar to the package shown in Figure 1 in the application. An additional benefit of shorter side walls and ridge walls, and in combination with the flaring feature, is the urging of the ridge into the recess and into a sealing relationship. In other words, there is a bias towards the sealing of the blister as a result of the complimentary flaring.

The final additional feature of the claimed invention is the difference in the length and width dimensions of the ridge 22 versus the corresponding dimension of the undercut 21. As set forth near the bottom of page 5 of the specification (and as claimed in claims 16 and 17), the larger ridge dimensions better forms an impermeable seal with the undercut. There is a bias or internal pressure urging the ridge walls outwardly against the undercut. Turning to Figure 3, for instance, the cross section shown could be either length or width. When the dimension of the ridge is greater than that of the recess, then the arrows show the force pushing the ridge outwardly to create a better seal with the recess.

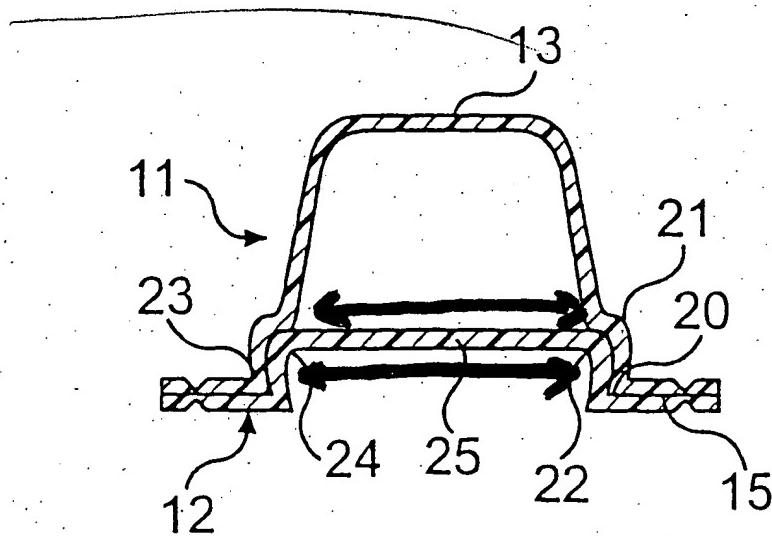


FIG. 3

As noted in the example in the specification at the bottom of page 5, the dimensions are not necessarily largely different. Applicant has found that a ridge having dimensions .002 inches larger than corresponding undercut dimensions can form a successful impermeable seal.

In summary, Applicant has invented a blister package that has an impermeable seal without using any adhesive. The specific, claimed invention should prove to be a substantial step forward in this field, as both "heat" and "adhesive" sealing methods currently used can be harmful to pharmaceuticals.

6. ISSUE

Whether the prior art references cited by the Examiner, alone or in the combinations cited, render Applicant's invention unpatentable.

7. GROUPING OF CLAIMS

In general, the groupings of claims discussed in connection with each of the Examiner's rejections is acceptable to Applicant for purposes of this appeal. Applicant notes, however, that there are some instances where the Examiner has not made specific rejections with reference to specific claims. Those specific instances will be taken up as they arise. Applicant intends to address each of the grounds of rejections in the order presented by the Examiner in the most recent rejection.

8. ARGUMENT

As will be demonstrated in the following discussion, the claimed invention of Applicant is new and nonobvious over the prior art references cited by the Examiner. Applicant believes that the rejections by the Examiner are the result of a misunderstanding of the claimed invention. Applicant had earlier made a trip to have a personal interview with the Examiner during which the invention was specifically explained; however, the Examiner's continued rejections indicate his continued misunderstanding of the invention. Applicant also notes that the present rejection mailed September 24, 2002 is a

nonfinal rejection in this Request for Continued Examination application. It is because of the Examiner's consistent misunderstandings in the three Office Actions in connection with this application that Applicant is compelled to file this appeal.

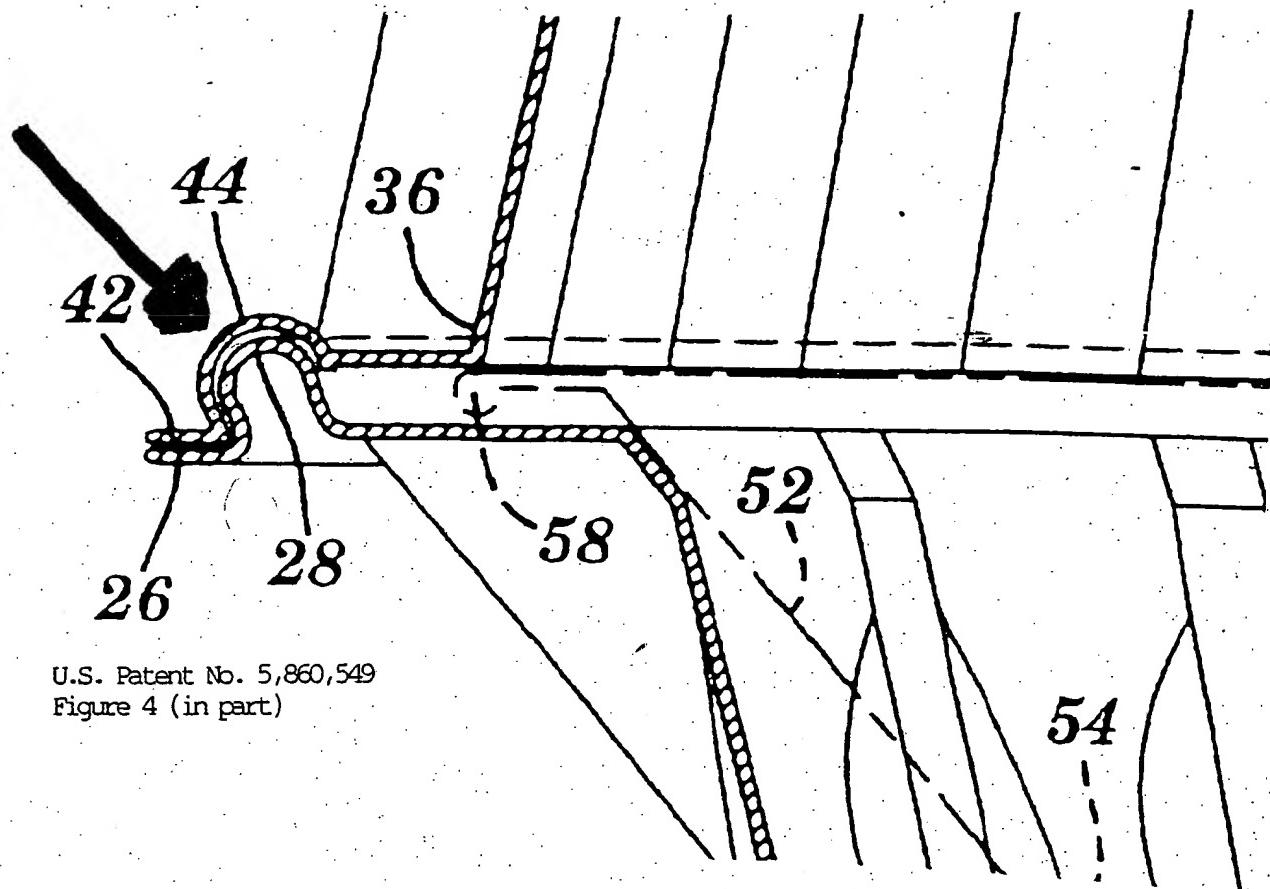
In the following arguments, Applicant will attempt to simplify the review in this appeal by tracking the references and bases for rejections relied upon by the Examiner in the order in which they were raised by the Examiner. In broad terms, there are two purportedly anticipatory references cited. There is also a short group of rejections based on obviousness. The three subsections of this argument will take up and analyze the two anticipatory references and the obviousness rejections.

- A. "Claims 1, 3, 6-14, 16 and 17 are rejected under 35 U.S.C. § 102 (b) as being anticipated by Allers et al.(Patent No. 5,860,549)." (Office Action dated September 24, 2002, paragraph 2).

The Allers reference is a container for housing a food dish. It is a variation of a classic "clam-shell" or pie dish package that is used to hold plates or dishes of food. While the Allers reference has some components that conceptually correspond to portions of the claimed invention, there are important differences.

With respect to claims 1, 3, and 9, and the Examiner never specifically referenced claim 9, the Examiner makes no allowance for the limitation in those claims that the engagement of the ridge and undercut forms "an impermeable seal". The Allers specification, specifically columns 4 and 5, includes discussion regarding sealing of the Allers container; however, the drawings of the Allers container clearly demonstrate that the discussion in the Allers patent relates to the clam-shell field where a seal is not necessarily impermeable. Referring specifically to Figure 4 in Allers as the Examiner does, there is shown a gap between the top and bottom components of the shell between the arcs 44 and 28.

See Allers et al.
col. 5, lines 1-2



U.S. Patent No. 5,860,549
Figure 4 (in part)

Accordingly, the Allers patent does not actually teach or enable a seal that could be characterized in any way as an impermeable seal as in the claimed invention. Since the requirement of an impermeable seal is a specific limitation in claim 1 (and therefore 3 and 9), and since Allers does not include, nor could it include, an impermeable seal, it is not an appropriate anticipatory reference.

More importantly than just claims 1, 3 and 9, and because Allers does not have or suggest an impermeable seal, Allers is not an appropriate anticipatory reference for any of the claims of the present application. The discussion of a seal in the context of a pie shell is simply not applicable to a discussion, much less a claim limitation, of an impermeable seal.

Specifically, with respect to claims 6-8 the Examiner suggests that the Allers reference teaches the use of polyethylene as a polymer to obtain an impermeable seal in accordance with the present invention. The broad, conclusory statement by the Examiner is purportedly supported by an equally broad and nonspecific statement in the Allers reference. There is no specific

reference to polyethylene in Allers. On the contrary, the use of polyethylene is explicitly described in the present application as being a particularly acceptable polymer for reasons of its "softness" and sealability. The Examiner is not entitled to make a statement that this limitation is in the Allers reference without a specific teaching.

With respect to claim 10, there is no teaching in the Allers reference that the undercut side walls are shorter than the ridge walls. The Examiner's reference to Figure 4 is not specific. Without a specific basis to rebut, it is impossible to reasonably counter an argument that does not exist. In fact, a reasonable study of Figure 4 literally suggests the contrary. The corresponding wall structures in Allers are apparently the same height. The claimed shorter side walls and the benefits of the shorter side walls are nowhere found in the Allers reference.

With respect to claims 11 and 12, the discussion earlier regarding the sealing attributes of the Allers reference indicates that there is clearly no ability for Allers to meet the functional requirements set forth in claims 11 and 12 with respect to an impermeable seal. A rejection based on Allers is not appropriate, because there is simply no indication of any sealing attributes therein.

With respect to claim 13, the Examiner makes the assumption that since Allers could literally, physically receive a medication, that it is in fact a package assembly for dispensing pharmaceutical medications. The Examiner makes no reference to claim 14, but it is presumably intended to be included there. But, there is simply nothing in the Allers reference or otherwise referred to in any reference cited by the Examiner that the clam-shell or pie dish of Allers could be acceptable as a medication package. The field of medication packaging is substantively and substantially different from the food package that constitutes the Allers invention. (There are completely separate classifications in the Patent Office Manual of Classification that address these technologies.) The

conclusory opinion by the Examiner, without support in the Allers reference or any other references that would indicate that the arts are analogous, is not a justifiable rejection. The Examiner cites support for his conclusion that a new use does not make an old product patentable. Unfortunately, the present invention is not a new use of an old product but a new use and a new product. The Examiner's rejection of claims 13 (and 14) is not justified.

Finally, with respect to claims 16 and 17, the Examiner cannot point to any teaching in Allers where the length and width of a ridge is larger than the corresponding dimensions of an undercut. As demonstrated in the summary of the invention earlier, the length and width dimensions are explicitly taught in order to obtain the explicit benefit of a good seal between the ridge and undercut. There is no teaching of greater length and width dimension in Allers. There is no suggestion or other justification of a finding of different length and width dimensions in Allers. This rejection is unjustified.

- B. "Claims 1, 3-14, 16 and 17 are rejected under 35 U.S.C. § 102 (b) as being anticipated by Edwards et al. (Patent No. 5,339,973)." (Office Action dated September 24, 2002, paragraph 3.)

Like the Allers reference already discussed, the Edwards reference discloses a container for storing food. In fact, the Edwards patent is owned by the same assignee of record as the Allers patent. The actual construction set forth and claimed in the Edwards patent is merely a specific variation of a "clam shell" or pie dish like in Allers.

At the outset, all of the rejections by the Examiner on the basis of the Edwards reference should fail, because there is no explicit teaching or other enablement of an "impermeable" seal in Edwards. There is discussion of the snap lock in Edwards, but there is no mention that the seal is impermeable. A specific discussion in Edwards suggests the contrary. In column 3 lines 16-19, there is mention that the outer surface of flange 38 has a radius approximately equal to the radius of the inner surface flange 40. While there is discussion of

a tight seal, there is no explicit teaching of an impermeable seal as in the claimed invention. An approximate similarity in shape as noted above does not create an impermeable seal.

The rejection of claims 11-13, 16 and 17 by the Examiner are literally duplications of the same rejection made early in connection with the Allers reference. (This is not surprising given the similarity of the nature of the prior art references and their common ownership). However, the rejection of all of these claims fails for all of the reasons noted earlier in connection with the Allers reference. The Edwards reference simply does not discuss the impermeability of a seal. It does not discuss a medication package assembly. The Edwards undercut sidewalls are not disclosed as shorter than ridge walls. It does not discuss or claim or disclose in any manner the length and width dimensions of the ridge versus the undercut. For virtually all the reasons that Allers fails as an anticipatory reference, so does Edwards.

C. Claim rejections under 35 U.S.C. § 103 (a)

Claims 4 and 5 are rejected as being unpatentable over Allers in view of Edwards. Unfortunately, the Examiner still fails to cite the claimed impermeable seal in either Allers or Edwards. Therefore, any combination of these references is not and cannot include all of the limitations of the claimed inventions in claims 4 and 5.

Claims 6-8, 11 and 12, are being rejected as being obvious over Allers alone. According to the Examiner the variations cited in those claims would be a matter within a general skill of a worker in the art. Unfortunately, the Examiner has once again failed to carry his burden of having any basis for why these variations would be obvious. Applicant has made its application on the basis that the claimed products, and specifically the products made of polyethylene are different and perform in an effectively unexpected, impermeable way. Clam shell-type packages must open as easily as they are

closed, so it would be known to those of skill in the art to use a material with high lubricity. Pharmaceutical packaging desires "more difficult" opening than sealing, so polyethylene is preferred by applicant for this attribute. The assumption of polymer selection in Allers is unjustifiable. Therefore, the Examiner's conclusion is not acceptable. The obviousness rejection cannot stand without further support.

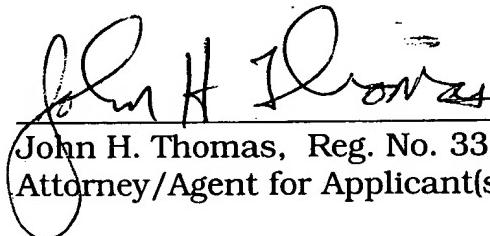
Finally, the Examiner has rejected claims 2 and 15 as being obvious over Zimmerman and in view of Allers or Edwards. In each of these rejections, (whether combined with Allers or Edwards), there is no justification for why the completely different packaging arts would be appropriately combined. There is no suggestion in a food package as shown in Edwards or Allers that there would be multiple sealed blisters. Likewise, the packaging in Zimmermann is not intended to be impermeable. It is meant to be easily accessed once the package is opened. There is simply no reasonable combination of these types of references. This obviousness rejection must be reversed.

D. Summary

As is evident from the facts and arguments set forth herein, Applicant's invention could be significant in the industry based on its ability to form an impermeable package without adhesives or heat sealing. The present invention, and specifically the various features of the claimed undercut and ridge dimensions and interactions, are new. They have never been seen before and with respect to obviousness, could not have been seen before. For one or more of the reasons set forth in this brief, Applicant's claims should be allowed. Favorable action is requested hereon.

The Commissioner is hereby authorized to charge any fees associated with this Appeal or credit any overpayment to Deposit Account No. 50-2127.

Respectfully submitted,


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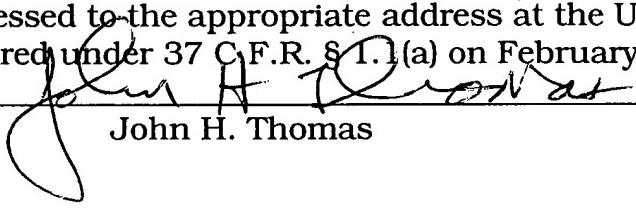
Attorney Docket No.: MULTI 9

Date: February 3, 2003

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to the appropriate address at the U.S. Patent and Trademark Office required under 37 C.F.R. § 1.1(a) on February 3, 2003.

by:


John H. Thomas

9. APPENDIX

1. (Amended) A sealed blister assembly comprising:
 - a plastic sheet having a recess formed therein, the recess having a perimeter all around an opening into the recess, and the perimeter further comprising an undercut;
 - a plastic lid adapted to attach to the perimeter of the recess and cover the opening into the recess, the plastic lid comprising a raised ridge having an outside edge adapted to engage the undercut of the plastic sheet around the entire perimeter,
 - wherein the engagement of the ridge and undercut forms an impermeable seal, whereby a sealed blister is formed from the plastic lid and the recess of the plastic sheet.
2. The sealed blister assembly described in claim 1, wherein the plastic sheet comprises a plurality of recesses, and wherein the plastic lid comprises a corresponding plurality of ridges to form a plurality of sealed blisters.
3. The sealed blister assembly described in claim 1, wherein the outside edge of the ridge comprises walls that flare outwardly.

4. (Amended) The sealed blister assembly described in claim 1, wherein the undercut comprises sidewalls, the outside edge of the ridge comprises walls, and further wherein the inside of the sidewalls are in frictional engagement with the outside edge of the ridge walls.
5. (Amended) The sealed blister assembly described in claim 3, wherein the undercut comprises sidewalls, and further wherein the inside of the sidewalls are in frictional engagement with the outside edge of the ridge.
6. The sealed blister assembly described in claim 1, wherein the plastic sheet is comprised of polyethylene.
7. The sealed blister assembly described in claim 1, wherein the plastic lid is comprised of polyethylene.
8. The sealed blister assembly described in claim 6, wherein the plastic lid is comprised of polyethylene.
9. The sealed blister assembly described in claim 5, wherein the undercut sidewalls flare outwardly in a corresponding fashion to the flared ridge walls.
10. The sealed blister assembly described in claim 4, further wherein the undercut sidewalls are shorter than the ridge walls.

11. The sealed blister assembly described in claim 1, further wherein the sealed blister is used for packaging a medication and the sealed blister meets or exceeds the requirements to be a U.S.P. Class A individual unit-dose container.

12. The sealed blister assembly described in claim 1, further wherein the sealed blister is used for packaging a medication and the sealed blister meets or exceeds the requirements to be a U.S.P. Class B individual unit-dose container.

13. (Amended) A package assembly for dispensing a pharmaceutical medication comprising:

a plastic sheet having a medication receiving recess formed therein and with a substantially planar shoulder portion disposed along the peripheral portion of the sheet and further with a perimeter around the recess;

a pharmaceutical medication positioned in said recess of said plastic sheet;

a plastic lid positioned in an overlying relationship to the plastic sheet, the plastic lid comprising a raised ridge having an outside edge corresponding to the perimeter of the recess and frictionally engaging the perimeter to thereby close the recess and impermeably seal the medication therein.

14. The package assembly set forth in claim 13, wherein the perimeter further comprises an undercut, and the ridge frictionally engages the undercut to seal the medication therein.

15. The package assembly set forth in claim 13, wherein the plastic sheet comprises a plurality of recesses, wherein pharmaceutical medication is positioned in each recess, and wherein the plastic lid comprises a corresponding plurality of ridges to form a plurality of medication - containing sealed blisters.

16. (Amended) A sealed blister assembly set forth in claim 1, wherein the length and width dimensions of the ridge are larger than the corresponding dimensions of the undercut.

17. (Amended) A package assembly set forth in claim 14, wherein the length and width dimensions of the ridge are larger than the corresponding dimensions of the undercut.